6. 510(k) Summary

K111887

SEP - 9 2011

A. Submitter

Covidien
15 Hampshire St.
Mansfield, MA 02048
Phone: 508-452-4135

B. Contact Person

Daniel Campion
Manager Regulatory Affairs

C. Date Prepared

June 30, 2011

D. Trade/Proprietary Name

Closure*FAST*™ Radiofrequency Catheter

E. Common/Usual Name

Electrosurgical Device

F. Classification Name

Electrosurgical cutting and coagulation device and accessories

G. Predicate Device(s)

Closure*FAST*™ Catheter (K061373)

H. Device Description

The Closure*FAST*™ Radiofrequency Catheter is provided sterile, and is a single-use, disposable device. It has a 3cm radiofrequency heating element, a flexible shaft, and an integrated instrument cable. It is designed for use with the VNUS RFG2 Generator, cleared under 510(k) K040638.

I. Intended Use

The Closure*FAST*™ Radiofrequency Catheter is intended for endovascular coagulation of blood vessels in patients with superficial vein reflux.

J. Technology Characteristics

The Closure*FAST*™ Radiofrequency Catheter is identical to the predicate device in terms of its intended use and fundamental scientific technology.

The function of the Closure*FAST*™ catheter is to coagulate blood vessels by delivering radiofrequency energy to a heating element on the distal end of the catheter that is positioned at a desired treatment site. The device now will be offered with a 3cm heating element, therefore allowing physicians to treat refluxing vein segments less than 7cm in length.

K. Materials

The Closure*FAST*™ Radiofrequency Catheter is composed of the same materials as the predicate device.

L. Performance Data

Testing was performed on the proposed Closure*Fast* to compare it to the predicate device. Testing included Design Verification and Validation on catheter compatibility, design specifications and performance. Results from the testing demonstrate that the modified device is substantially equivalent to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Covidien
% Mr. Daniel Campion
Regulatory Affairs
Vascular Therapies
15 Hampshire St.
Mansfield, MA 02048

SEP - 9 2011

Re: K111887
Trade/Device Name: Closure*Fast* Radiofrequency Catheter
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: August 10, 2011
Received: August 12, 2011

Dear Mr. Campion:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (if known): K111887

Device Name: Closure*FAST*™ Radiofrequency Catheter

Indications for Use: The Closure*FAST*™ Radiofrequency Catheter is intended for endovascular coagulation of blood vessels in patients with superficial vein reflux.

Prescription use __X__ (Part 21 CFR 801 Subpart D) **AND/OR** **Over-The-Counter Use** _____ (Part 21 CRF 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of ___

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111887